REMARKS

Please amend claim 48 for proper dependency, as indicated. Please amend Claims 37 and 53. Support for the independent claim amendments can be found, at least, in the specification, e.g., paragraphs [0004], [0025]-[0027], [0030] and [0034]-[0035] of the specification as published, and the figures, e.g., figures 1 and 2 showing a control module 80 having computing elements (i.e. processor) and referring to a software algorithm. No new matter has been added.

Support for Claims Amendments

Support for the amendments to independent claims 37 and 53 exist throughout the specification and at least in paragraphs [0004], [0025]-[0027], [0030] and [0034]-[0035] of the specification as published, and the figures, e.g., figures 1 and 2, reproduced here for convenience:

> [0004] … Furthermore, there is a need for an automated interactive cell processing system that can assure uniform and reproducible processing condition of the same type of cells ***regardless of their amount being processed or the processing location***.
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> [0025] Referring to FIGS. 1 and 3, an interactive cell processing system 10 includes a cell module 12, a supply module 20, a fluid distribution module 40, a processing module 60, a collection module 70 (not shown in FIG. 1) and ***a control module 80***. These modules are operatively interconnected for processing biological cells in a sterile environment.
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> [0026] In general, the operation of cell processing system 10 is shown in FIG. 2. Control module 80 executes a processing algorithm selected initially (98). Control module 80 ***includes a logic controller that receives real-time data from several in-line sensors arranged in a processing loop***.
>
> [0027] Control module 80 ***executes iteratively the processing algorithm***. Control module 80 receives data from the ***individual sensors (e.g., a weight sensor, a volume sensor, a temperature sensor, an optical sensor, a resistance or capacitance sensor, a flow sensor, a pressure sensor or another sensor arranged to monitor the transferred matter in a liquid, gaseous or solid state***). After dispensing the selected amount of one or several processing chemicals to processing module 60, control module 80 regulates the temperature and the time of processing and directs the processing module to agitate, mix or otherwise treat the cells with the process chemicals.

> [0030] Processing module 60 is designed to assure identical processing conditions (e.g., pressure, temperature, mixing, processing time or other) ***for large and small amounts of the biological cells provided for processing***. For this purpose, processing module 60 includes a processing chamber that has a variable volume design. Depending on the volume of the processed cells and other processing chemicals transferred into the processing chamber, the controller changes the chamber volume. The volume change is achieved by a movable wall that may be a membrane. Processing module 60 includes another ***pressure sensor for measuring the pressure inside the processing chamber and also includes a temperature sensor for measuring the temperature inside the processing chamber***. Based on the data from the temperature sensor, a heat transfer system can provide or remove heat from the processing chamber.
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> [0034] ***The controller controls the volume of the processing chamber of centrifuge 62 to assure identical processing conditions for large or small amounts of the red blood cells***. The processing chamber includes a flexible wall for containing expresser fluid. For small volumes, ***expressor system 64 pumps expressor fluid into the chamber until the pressure transducer at the chamber signals a full condition. This pre-filling step assures that different amounts of red blood cells are subjected to the same accumulated centrifugal force and mechanical stresses due to packing. Otherwise, smaller amounts would spin longer and pack harder as the expresser fluid fills the processing chamber during the expression step***.
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> [0035] During the process, ***the controller receives input from IR temperature sensor 6***6, which measures the temperature of the RBCs. If the temperature is less than the set point, expressor of system 64 increases the temperature of the expressor fluid. Conversely, if the temperature is greater than the set point, expresser of system 64 decreases the temperature of the expresser fluid. ***A control loop continuously monitors the temperature of the processed cells***. [Emphasis added]

The control module comprises a "logic controller" which is a well-known computing component of a processor that processes algorithms.

Regarding Rejections Under 35 USC 103(a)

The Office Action rejected claims 37-41, 44-45, 48, 51-54 and 56-63 under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,544,727 to Hei ("Hei") in view of US Patent No. 4,530,691 to Brown ("Brown") in view of US Patent 5,428,993 to Kobashi ("Kobashi"), in view of

US Patent No. 4,379,452 to DeVries ("Devries") and in view of US Patent 4,450,375 to Siegal ("Siegal"). Applicant respectfully traverses this rejection.

Applicant respectfully disagrees with this rejection as applied to independent claims 37 and 53 as currently amended. As indicated in the support provided above as well as the now amended claims, the present invention includes a controller that receives data from a plurality of sensors and continuously controls the processing module to maintain processing conditions *substantially independent of an amount of biological cells provided for processing.* Support exists throughout the specification and figures, for example paragraphs [0004], [0025]-[0027], [0030] and [0034]-[0035] of the specification as published and FIGS. 1 and 2.

Pages 4 and 5 of the instant Office Action contains language characterizing Hei as teaching all of the elements of independent claims 37 and 53, and includes the following remarks:

> Hei discloses a plurality of sensors, and specifically a sensor calculating the volume and weight of fluids (Col. 65, line 30-47). Hei discloses controlling temperature (Col. 71, line 63-65; Col. 72, line 55-64)…Hei discloses an expression system (Col. 97, line 40-67).
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> Hei does not show a variable volume processing chamber that is under control of a controller.

Page 6 of the instant Office Action contains language characterizing Brown as teaching an apheresis system comprising a variable-volume processing chamber (Abstract) and Kobasih as disclosing a weight sensor for chemical reagents to be used in automatic analyzers that confirms correct delivery of a chemical by measuring change in weight (column 2, lines 1-25). Page 6 of the instant Office Action also contains language characterizing DeVries as showing fluid distribution through conduits for processing cells, and Page 7 of the instant Office Action contains language characterizing Siegal as teaching a control module comprising a plurality of channels, ports and selectively opened valves.

Applicant respectfully submits that the proposed combination of art fails to teach, suggest or otherwise make obvious the limitations of independent claims 37 and 53 as currently amended. Namely, the proposed combination of art fails to teach , suggest, or otherwise make obvious a processor that is configured to receive data from the plurality of sensors and continuously control the processing module to maintain processing conditions substantially independent of an amount of biological cells provided for processing. These continuously and interactively adjusted parameters, such as the temperature and

pressure within the processing chamber, advantageously enable the system to process cells similarly regardless of the volume of biological cells introduced into the processing chamber.

Hei describes a system for the decontamination of biological fluids as well as methods and devices for the removal of psoralens and psoralen photoproducts from blood products. (*See* Abstract.) Hei includes an exemplary apheresis system having fluid pumps, a centrifuge, fluid lines, and a computerized controller "connected to various sensors that monitor fluid volumes, contaminants and the like." (Col. 66, lines 40-65; see also FIG. 49.) Hei, however, fails to teach, suggest or otherwise make obvious a processor configured to receive data from the plurality of sensors and continuously control the processing module to maintain processing conditions substantially independent of an amount of biological cells provided for processing. Furthermore, the sensors controlled by the computerized controller of Hei are extraneous to the chamber containing biological cells, and thus teaches away from the presently claimed invention. For example, in "Example 1" at column 71, lines 63-65 and column 72, lines 55-64 of Hei teaches a housing in which bags ("containing means") of already-processed blood product are placed for illumination:

> FIG. 1 is a perspective view of one embodiment of the device integrating the above-named features. The figure shows an opaque housing (100) with a portion of it removed, containing an array of bulbs (101) above and below a plurality of representative blood product containing means (102) placed between plate assemblies (103, 104). The plate assemblies (103, 104) are described more fully, subsequently.
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> FIG. 3 is a cross-sectional view of the device shown in FIG. 1 along the lines of 3--3. Six blood product containing means (102) (e.g. Teflon.TM. platelet unit bags) are placed in a fixed relationship above an array of bulbs (101). The temperature of the blood product can be controlled via a fan (112) alone or, more preferably, by employing a heat exchanger (113) having cooling inlet (114) and outlet (115) ports connected to a cooling source (not shown).

Furthermore, Hei also includes an external heat exchanger that controls the temperature of the six blood product containers via a fan and a heat exchanger. As stated above, Hei fails to teach, suggest or otherwise make obvious a processor for continuously controlling a biological cell processing module to maintain processing conditions substantially independent of an amount of biological cells provided for processing. In contrast, the instant device is for enzymatic manipulation of biological cells, and the parameters of the reaction inside the processing chamber need to be controlled with precision independent

of the amount of biological cells provided for processing. Hei, therefore, teaches away from the now claimed invention.

Brown fails to cure the deficiency of Hei either alone or in combination with Kobashi, DeVries, and/or Siegal. Language on page 6 of the instant Office Action characterizes Brown as showing "an apherisis system comprising a variable-volume processing chamber and a controller that controls the volume of the processing chamber (Abstract)." Brown describes a variable-volume chamber that includes a mandrel that applies a "conforming force to the chamber by urging the chamber toward the cover and thereby causing the chamber to conform to the shape of the cover…the cover and mandrel cooperate in controlling the volume and shape of the chamber." The mandrel retracts as the chamber of the device fills with blood. (*See* Abstract.) Brown describes a simple mechanical reaction caused by the addition of blood to the processing chamber. Like Hei, Brown fails to teach, suggest or otherwise make obvious a processor configured to receive data from a plurality of sensors and continuously control a processing module to maintain processing conditions substantially independent of an amount of biological cells provided for processing. Brown, in fact, fails to teach, suggest or otherwise make obvious any processor or sensor.

Kobashi describes an automatic analyzer having a function for detecting a remaining quantity of liquids being used. (*See* Abstract.) As described at column 4, lines 50-58, in relation to FIG. 2, a reagent container 12 is connected to the analyzer 10 through a tube 14. The container 12 is put on a weigh sensor 16, and a weight of the container 12 is transmitted to the analyzer for processing. Like Hei and Brown, Kobashi fails to teach, suggest or otherwise make obvious a processor configured to receive data from a plurality of sensors and continuously control a processing module to maintain processing conditions substantially independent of an amount of biological cells provided for processing.

DeVries describes a compact and disposable monitor and fluid circuit assembly for collecting a desired blood component (Col. 1, lines 19-23). The monitor and fluid circuit assembly 11 is described as including a fluid circuit 16 including a plurality of flexible plastic tubes that form fluid couplings between various parts of the fluid circuit 16 (Col. 3, lines 1-8). The tubes are described as being received through a housing 18 that has monitor devices therein (Col. 3, lines 9-10). The tubing is described as being series coupled to a high pressure monitoring device 64 (Col 3, lines 56-59). In reference to FIG. 5, the monitoring device includes an air filled closed chamber 184 having a flexible diaphragm 135 forming part of one wall of the flow through chamber and an outer wall 136 situated adjacent an associated pressure transducer (Col. 7, lines 51-55). The outer wall 136 in DeVries is situated adjacent a sensor 63, 63, or 85

"which are pressure transducers and which sense pressing on the outer wall 136." (Col. 7, lines 50-56). Like Hei, Brown, and Kobashi, however, DeVries fails to teach, suggest or otherwise make obvious a processor configured to receive data from a plurality of sensors and continuously control a processing module to maintain processing conditions substantially independent of an amount of biological cells provided for processing.

Siegal describes a "piezoceramic bend [that] cooperates with an impacting member, membrane and valve seat to provide a novel piezoelectric transducer arrangement for achieving desired rapid and accurate control of fluids under pressure in a variety of different applications." That is, Siegal describes a fluid control device for use in selectively dispensing desired quantities of fluid using a piezoelectric device. (See Abstract.) Siegal does not cure the deficiencies of the other cited references with respect to describing, suggesting or otherwise making obvious a processor configured to receive data from a plurality of sensors and continuously control the processing module to maintain processing conditions substantially independent of an amount of biological cells provided for processing.

For these reasons, the proposed combination of fails to teach, suggest, or otherwise make obvious the elements of independent claims 37 and 53, as currently amended. Accordingly, Applicant respectfully submits that independent claims 37 and 53 are in condition for allowance, and Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Claims 38-45, 48-52 and 54-67 depend from and add to now amended claims 37 and 53 and are allowable for the same reasons. Applicant respectfully requests the withdrawal of the rejection of claims 38-45, 48-52 and 54-67.

The Office Action rejected claims 42-43 under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,544,727 to Hei ("Hei") in view of US Patent No. 4,530,691 to Brown ("Brown") in view of US Patent 5,428,993 to Kobashi ("Kobashi"), in view of US Patent No. 4,379,452 to DeVries ("Devries") and in view of US Patent 4,450,375 to Siegal ("Siegal") as applied to claims 37-41, 44-45, 48, 51-54 and 56-63 above and further in view of US Patent No. 5,126,054 to Matkovich ("Matkovich"). Applicant respectfully traverses this rejection.

Applicant respectfully submits, as set forth already in the preceding arguments, that the proposed combination of references fails to teach, suggest or otherwise make obvious independent claims 37 and 53 as currently amended because dependent claims 42-43 depend on claim 37 and include all limitations thereof as well as adding additional limitations to claim 37. Applicant respectfully submits that

dependent claims 42-43 also are in condition for allowance. Applicant therefore requests reconsideration and withdrawal of the present rejection.

The Office Action rejected claims 49 and 50 under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,544,727 to Hei ("Hei") in view of US Patent No. 4,530,691 to Brown ("Brown") in view of US Patent 5,428,993 to Kobashi ("Kobashi"), in view of US Patent No. 4,379,452 to DeVries ("Devries") and in view of US Patent 4,450,375 to Siegal ("Siegal") as applied to claims 37-41, 44-45, 48, 51-54 and 56-63 above and further in view of US Patent No. 3,478,673 to Burney et al. ("Burney") and in view of US Patent No. 4,937,196 to Wrasidlo et al. ("Wrasidlo"). Applicant respectfully traverses this rejection.

Applicant respectfully submits, as set forth already in the preceding arguments, that the proposed combination of references fails to teach, suggest or otherwise make obvious independent claims 37 and 53 as currently amended because dependent claims 49 and 50 depend on claim 37 and include all limitations thereof as well as adding additional limitations to claim 37. Applicant respectfully submits that dependent claims 42-43 also are in condition for allowance. Applicant therefore requests reconsideration and withdrawal of the present rejection.

The Office Action rejected claim 55 under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,544,727 to Hei ("Hei") in view of US Patent No. 4,530,691 to Brown ("Brown") in view of US Patent 5,428,993 to Kobashi ("Kobashi"), in view of US Patent No. 4,379,452 to DeVries ("Devries") and in view of US Patent 4,450,375 to Siegal ("Siegal") as applied to claims 37-41, 44-45, 48, 51-54 and 56-63 above and further in view of US Patent No. 5,641,637 to Hudak ("Hudak"). Applicant respectfully traverses this rejection.

Applicant respectfully submits, as set forth already in the preceding arguments, that the proposed combination of references fails to teach, suggest or otherwise make obvious independent claims 37 and 53 as currently amended because dependent claim 55 depends on claim 53 and includes all limitations thereof as well as adding additional limitations to claim 53. Applicant respectfully submits that dependent claim 55 also is in condition for allowance. Applicant therefore requests reconsideration and withdrawal of the present rejection.

New Claims

With regard to the new dependent claims, Applicant respectfully submits that support for this claimed subject matter exists throughout the specification and at least at specification paragraphs [0030], [0034] and [0035], reproduced above in response to the rejections under 35 USC 103(a). New claims 64-67 add additional limitations to dependent claims 37 and 53, particularly with regard to the sensors in communication with the processor of the control module now claimed in amended claims 37 and 53. None of the above-cited references, taken either alone or in combination, teach, suggest or otherwise make obvious the placement of a temperature sensor or pressure sensor inside of a biological cell processing chamber for enabling a processing module to maintain processing conditions substantially independent of an amount of biological cells provided for processing. Applicant therefore respectfully submits that newly added dependent claims 64-67 are in condition for allowance.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application, or credit any overpayment, to Deposit Account No. 50-4514. Should proper payment not be enclosed herewith, resulting in a rejected or incorrect payment transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-4514.

Respectfully submitted,

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